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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/592,695	06/13/2000	Andrea G Cochran	P1762R1	7146

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Steven X Cui
Genentech INC
1 DNA Way
South San Francisco, CA 94080-4990

EXAMINER
WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
1639	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/592,695	Applicant(s) COCHRAN ET AL.	
	Examiner T. D. Wessendorf	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-14 and 19-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-14 and 19-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Claims

Claims 4 and 15-18 have been canceled in the Present Amendment, 12/26/02.

Claims 19-22 have been added in the Present Amendment.

Claims 1-3, 5-14 and 19-22 are under examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 and 5-14 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility for the reasons set forth in the last Office action (8/28/02).
The rejection of the claim as being drawn to non-statutory subject matter is withdrawn in view of the amendments to the claims.

Response to Arguments

The response is with respect to the lack of patentable utility for the claimed library.

Applicants argue that as described in the utility guidelines, screening assays for identifying compounds that have a substantial utility define a real world context of use. In response, firstly, the claims are drawn to

libraries, not to a screening assay. Secondly, as stated by applicants the screening assay will identify compounds that have a substantial utility. The library, in of itself, does not have a utility. Rather, the compounds contained therein. This is analogous to compositions that are present in nature. It is a complex make-up of all kinds of components that are screened. The purpose of screening is to isolate and identify a particular compound that has the specific utility. This is evident from applicants' statement that "the peptide library can be screened against biological molecules to identify members of the library that bind to a particular biological molecule." (Emphasis ours).

> "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner*, 148 USPQ at 696.

In *Brenner*, the Court approved a rejection for failure to disclose any utility for a compound where the compound was undergoing screening for possible compounds the utility of which has also not been identified. *Brenner*, 148 USPQ at 690. Here, there is no evidence that the claimed isolated compounds have any utility. *See In re Kirk*, 153 USPQ 48, 53 (CCPA 1967) (quoting the Board of Patent Appeals, 'We do not believe that it

was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.') There is no evidence of record or any line of reasoning that would support a conclusion that the library of the instant application was, as of the filing date, useful. Except, perhaps, to make a collection of components. Until some actual and specific significance can be attributed to the library one of ordinary skill in the art would be required to perform additional experimentation.

Applicants submit that the invention provides methods and compositions of identifying a peptide capably binding a specific binding partner as described in the specification at page 11, lines 24-35. A review of the cited section discloses a method of screening a library of peptide to identify peptides having a β-hairpin scaffold. Just what exactly the utility even for the

identified peptide is unclear from this cited section. Applicants submit that the peptides **may be** useful as agonists or antagonists or can be **candidates** for therapeutic agents. As stated above, a sole 'utility' that consists of its potential role as an object of use-testing is not a utility as required by the statute.

Claim Rejections - 35 USC § 112

. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-14 and 19-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons advanced in the last Office action.

Response to Arguments

Applicants recite a number of factors to establish the written description for the invention. It is argued that base on these factors, applicants have described the structure of their

library of peptides and provided several examples of the peptide library. Example 2, at least is relied upon. A review of Example 2, page 27 reveals a structure activity study for the different compounds that will form a hairpin structure. There is no screening done for the claimed library. Only a structure activity studies was done. The study reveals a peptide with a stable hairpin structure by mutating amino acid residues of a known peptide containing the residues. Applicants state that "..we have synthesized a disulfide-constrained peptide based on the native sequence of the CD4 hairpin… and found it to be essentially unstructured in solution. We then made the substitutions G2T and N3, to match the corresponding residues in bhpW…residues L8 and T9 are already present in the native CD4 sequence. Peptide cd2 is well ordered, adopting a hairpin structure with type II' turn…"

It is argued that the library has specific utility in designing ligands that extend into the binding pocket of HIV gp 120. In response, it is not clear whether the specific utility is in designing ligands or screening the library. Designing a ligand from structure activity study is not a definite use of a library or a compound. Applicants further argue that the ligands have substantial utility in that they (1) can serve as antagonists (i.e., by occupying the binding pocket they inhibit

CD4 binding to gp 120 which is necessary for entry of HIV into cells) and (2) can be fused with antigenic epitopes thereby presenting exposed epitopes for virus-neutralizing antibodies.

It is not controverted that the ligands obtained from the library might have the argued capabilities. However, the issue is not with respect to the specifically obtained ligand, but to the claimed library itself. Just exactly what specific utility is served as for an antagonist is not clear. No specific utility of the antagonist is recited. Example 6 relates to a screening process, as argued. However, it does not relate to any specific use of the library. It relates to the isolation of clones (peptide) from the library (similar to a compound isolation from the complex composition of nature).

The following 35 U.S.C. 112, first paragraph rejection applies to the newly amended claims:

1. In claim 1, an "isolated" library is not supported in the as-filed specification. Also, in claim 20, "synthetic amino acids wherein n is 3 to 12, inclusive and isolated plurality" Applicants point support to page 10, line 4 and lines 8-15 and page 4, lines 16-22. None of these provides support for an **isolated** library. Page 10, line 29 recites only "naturally occurring L-amino acids", not synthetic as claimed. The specification does not provide a description for a library

wherein the residues are synthetic. It does not disclose any synthetic residues or what would constitute a synthetic residue in the context of the claimed library. An amendment to the claims or the addition of a new claim must be supported by the description of the invention in the application as filed. In re Wright, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989).

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In view of the amendments to the claims the rejection under paragraphs A and B no longer applies.

The following rejections apply to the newly amended claims:

1. It is not clear as to the library that is screened to isolate the claimed library.

2. In claim 19, "the amino terminus of C1 is optionally protected" broadens the base claim 1. Optional protection contains additional compounds not present in the base claim. The

rejection is also applicable to claim 22. It suggested that this limitation be incorporated to claim 1, as originally claimed.

3. Claim 20 is a duplicate of claim 1. The same library having the same structure is being claimed. Claim 20 contains only the limitation of a reverse turn secondary structure. This is also assumed by the identical structure of claim 1. The metes and bounds of the recited "synthetic amino acid" and "isolated plurality" are not clearly set forth or supported in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this

application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2, 4, 5, 8 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Wrighton et al [5,830,851(I)] for reasons stated in the last Office action.

The rejection of the claims over Wrighton(II) is withdrawn since the disclosure is the same as in Wrighton (I). The examiner appreciates applicants' comment that the rejection over Wrighton (II) should be under 102(b), not (e). However, since Wrighton (II) has the same disclosure as Wrighton (I), the rejection no longer applies.

Applicants argue that Wrighton et al(I) does not disclose at least the element that each cyclized peptide in the library includes a sequence:C1-A1-A2-(A3)n-A4-A5-C2. It is argued that the claims require all cyclized peptides in the library to comprise a specific set of amino acids where A1 and A5 must be W, Y, F, H, I, V or T and A2 and A4 must be W, Y, F, L, M, I, or V. The library of Wrighton I is argued to contain peptides outside of this requirement. The peptide of Wrighton, at col. 160, lines 1-12 is compared with the instant claimed peptide. For example, positions A1 and A5 in the Wrighton I library is said to be R, H, or L for A1 and D. E, I, L, or V for A5. A1 of the instant claim corresponds to X4 of Wrighton which is R, H,

L, or W. The subgeneric formula of Wrighton with A1 defined as W, H and L together with the species included in the subgenus fully meets the claimed invention.

If one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged." One may look to the preferred embodiments to determine which compounds can be anticipated. In re Petering, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

Applicants argue that A3 at positions 1, 2, and 4 are not constrained to specific amino acids when n equals 4. Attention is directed to example 4 where A3 is EGNK when n equals r. In response, applicants' argument is not commensurate in scope with the claims. The claims do not recite said specific EGNK sequence for A3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4, 5, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wrighton et al.

Some of applicants' arguments under the 102 rejections are repeated herein. The response to said arguments above is hereby incorporated. It is further argued that Wrighton does not teach or suggest that their library can accommodate a variety of peptide structures other than GPXT. Simply because Wrighton does not disclose the other peptides is not an indication that the peptides disclosed by Wrighton does not render the broad claimed library obvious. It is further argued that Wright does not teach the positions that provide for increased stability of the hairpin structures in solution. It would be within the ordinary skill in the art to determine such property given a known peptide sequence using known techniques as stated in the specification.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

REASSIGNMENT OF LOCATION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit **1639**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T. D. Wessendorf
Primary Examiner
Art Unit 1627

tdw
2/21/03